



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/049,871	10/03/2003	Yanina Rozenberg	271010-473	2364
27162	7590	11/02/2006	EXAMINER	
CARELLA, BYRNE, BAIN, GILFILLAN, CECCHI, STEWART & OLSTEIN 5 BECKER FARM ROAD ROSELAND, NJ 07068			WOITACH, JOSEPH T	
			ART UNIT	PAPER NUMBER
			1632	

DATE MAILED: 11/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/049,871

Applicant(s)

ROZENBERG ET AL.

Examiner

Joseph T. Woitach

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 15 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) 18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-17 and 19-23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

This application is a 371 of PCT/US00/22619, filed 08/18/2000, which is a continuation of 09/377,153 08/19/1999, now abandoned.

Claims 1-23 are pending.

### *Election/Restrictions*

Applicant's election of group I in the reply filed on August 15, 2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

With respect to the election of species, the elected species are noted. However, upon further consideration the Examiner does not consider it to be an undue burden to examine the genus and the specific species recited. Accordingly, the requirement is withdrawn.

Claims 1-23 are pending. Claim 18 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on August 15, 2006. Claims 1-17 and 19-23 are currently under examination.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

Art Unit: 1632

application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### ***Information Disclosure Statement***

The information disclosure statement (IDS) submitted are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

### ***Specification***

The disclosure is objected to because of the following informalities:

Upon review of the specification, identification of references to an Appendix is found (for example page 20, line 20). However, there is no appendix attached to the instant specification.

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

Claims 1-11, 16, 20-23 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by WO 96/21036.

WO 96/21036 discloses gene therapy vectors comprising retrovirus vectors containing a nucleic acid core, a viral capsid, a surface moiety derivatized with a synthetic immunoprotective polyethylene glycol polymer (p. 12, lines 7-10) and further comprising targeting elements and/or peptides (p. 27, lines 32-36, for example) and cell entry elements (adenovirus capsid proteins containing acid-activated lytic activity of the amphiphilic  $\alpha$ -helix of the penton-base protein; p. 28, lines 16-18 in view of well-characterized adenovirus vector properties).

Claims 1, 2, 4, 5, 10, 11, and 13-15 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by WO 92/06180.

WO 92/06180 discloses chemical coupling of galactose residues to a Moloney murine leukemia virus (MoMuLV) for targeting expression of  $\beta$ -galactosidase to asialoglycoprotein-positive cells (Example 1, p. 9). The Moloney murine leukemia virus disclosed contains a nucleic acid core, a surface moiety comprising a targeting element (galactose), a cell-entry element, comprising the MoMuLV envelope (which includes the C-terminal amino acids 598-616), and the MoMuLV capsid.

Claims 1, 3-8, 10-12, 17 and 20 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by WO 97/40854.

Art Unit: 1632

WO 97/40854 discloses DNA/polypeptide compositions (nonviral gene therapy vectors) containing a nucleic acid core and a surface moiety comprising immunoprotective, amphiphilic  $\alpha$ -helical glutamic acid/leucine copolymers (p. 3, lines 17-21, p. 7, lines 6-10, and pp. 9, lines 16 through p. 11, line 22) as cell-entry elements and additionally containing targeting elements to bind receptors upregulated in cancer cells (via folic acid, for example, see p. 27, line 35).

Claims 1, 5, 7, 10-12, 17 and 20 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Gottschalk et al. (Gene Therapy, 3:448-457, 1996).

Gottschalk et al. discloses peptide-nucleic acid conjugates/gene therapy compositions containing a nucleic acid core and a surface moiety comprising a synthetic immunoprotective/cell entry glutamic acid/leucine copolymer (GLFEALLELLESLWELLLEA) with  $\alpha$ -amphiphilic membrane destabilizing properties (see abstract, p. 448).

Claims 1-8, 10-11, 16 and 20-23 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Chillon et al. (Gene Therapy, 3:448-457, 1996).

Chillon et al. discloses adenovirus gene therapy vectors containing a nucleic acid core and a surface moiety comprising an adenovirus capsid, a targeting element (fiber protein) binding  $\alpha_v\beta_3$  integrin receptors upregulated in certain disease states, a cell entry element (adenovirus  $\alpha$ -amphiphilic membrane destabilizing penton base) and further comprising a synthetic immunoprotective polymer element, polyethylene glycol (see abstract, p. 995 in view of well-characterized adenovirus vector properties).

Art Unit: 1632

Claims 1, 2, 4, 5, 10-11, and 13-15 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Porter et al. (J. Virol., 72:4832-4840, 1998).

Porter et al. discloses cationic liposome-mediated cell fusion of MoMuLV retroviral gene therapy vectors using enveloped (ecotropic MoMuLV-E containing C-terminal *env* amino acids 598-616) and non-enveloped compositions comprising a nucleic acid core, and a surface moiety comprising a viral capsid (gag) and a targeting/cell-entry element comprising a membrane destabilizing amphiphilic  $\alpha$ -helix (*env*; see abstract, p. 4832 and Fig. 4B.1, p. 4837 in view of well-characterized MoMuLV vector properties).

Claims 1, 2, 4, 5, and 8-11 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Harbottle et al. (Hum. Gene Ther., 9:1037-1047, 1998).

Harbottle et al. discloses nonviral gene therapy vectors comprising a nucleic acid core and a polylysine/RGD-based targeting peptide surface moiety conjugated to a deactivated adenovirus further comprising viral capsid and cell-entry elements (acid-activated lytic activity of the amphiphilic  $\alpha$ -helix of the adenoviral penton-base protein; see abstract, p. 1037; Fig. 3, p. 1042; and Figs. 7 and 8, p. 1045).

Claims 1, 3, 5, 7, 10-12, 17 and 20 are rejected under 35 U.S.C. 102(e) as being anticipated by US 5,904,936.

US 5,904,936 discloses amphiphilic, immunoprotective poly (Leu/Glu) carriers (col. 12, lines 35-39 and Examples 1-9) of DNA for use in gene therapy (col. 1, lines 60-63).

Art Unit: 1632

Claims 1, 3-8, 10, 11, 16 and 20-23 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by US 5,908,777.

US 5,908,777 disclose nonviral gene therapy vectors comprising a nucleic acid/polylysine/20-mer amphiphilic  $\alpha$ -helical peptide core encapsulated into anionic liposomes further comprising additional targeting (folate receptor upregulated in cancer) and immunoprotective polymer elements (DOPE/CHEMS/folate-PEG-PE; column 7, lines 52-63; columns 9, 10, Example 2; column 10, Example 3; and Fig. 4 and 6).

Claims 1-7, 10, 11, 13, 16 and 20-23 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by WO 98/44143.

WO 98/44143 discloses PEG-modified recombinant viral vectors for gene therapy containing a nucleic acid core and a surface moiety comprising a synthetic immunoprotective polyethylene glycol polymer, a viral capsid, and targeting and cell-entry elements (including amphiphilic  $\alpha$ -helical membrane destabilizing moieties, especially in the adenoviral vectors; see abstract and claims in view of well-characterized adenoviral/ retroviral vector properties).

In light of the broad claims recited, the following examples of prior art, while not relied upon, are provided insmuch as they anticipate various embodiments covered by the present claims.

- 1) Meyer et al., J. Biol. Chem., 273(25):15621-15627 (June 19 1998).
- 2) Sharma et al., Proc. Natl. Acad. Sci. USA, 94:10803-10808 (September 1998).
- 3) Abe et al., J. Virol., 72(7):6159-6163 (July 1998).

Art Unit: 1632

- 4) Nakanishi et al., J. Controlled Release, 54:61-68 (June 1998).
- 5) US 5,891,468 Filing Date: 10/10/97 Date of Patent: 04/06/99
- 6) US 5,888,502 Filing Date: 06/05/95 Date of Patent: 03/30/99
- 7) US 5,908,635 Filing Date: 08/05/94 Date of Patent: 06/01/99
- 8) US 5,252,348 Filing Date: 07/30/92 Date of Patent: 10/12/93
- 9) US 5,789,230 Filing Date: 04/12/96 Date of Patent: 08/04/98
- 10) US 5,683,866 Filing Date: 05/09/96 Date of Patent: 11/04/97
- 11) US 5,693,509 Filing Date: 09/29/95 Date of Patent: 12/02/97

***Conclusion***

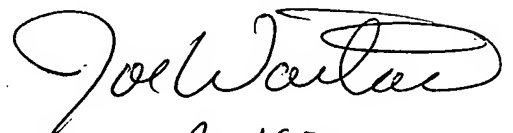
No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (571) 272-0739.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached at (571) 272-0735.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (571) 272-0532.

Joseph T. Woitach

  
A01632